

REMARKS

In the outstanding Office Action, claims 1-19 were rejected under 35 U.S.C. § 102(b).

As shown above, claims 2 and 4 have been amended, claims 1 and 3 have been cancelled, and new claims 20-26 have been added. Claims 2 and 4-26 are currently pending.

§ 102(b) Rejection of Claims 1-9 and 14-19

Claims 1-9 and 14-19 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,112,318 ("Novacek"). Applicants respectfully disagree.

Because claims 1 and 3 have been cancelled and claim 2 has been amended to depend from claim 4, the rejections of claims 1-3 under § 102(b) have been rendered moot.

Claim 4 Is Not Anticipated By Novacek

Claim 4 is directed to a cannula system comprising, in part, a cannula support comprising a thread turning in a first direction and another thread turning in a second, generally opposite direction and a protective cap having a thread engageable with the thread of the cannula support turning in the second generally opposite direction.

Novacek, on the other hand, discloses a syringe having a needle that can be retracted into the barrel of the syringe. It is asserted in the Office Action that Fig. 8 of Novacek depicts a protective cap having a thread engageable with said thread turning in said second generally opposite direction. However, the cap (32) shown in Fig. 8 does not have a thread, but rather "fits over" the hub (6). *See* Novacek, col. 14, ll. 66-67. Further, the hub (6) over which the cap (32) fits does not have a thread turning in a first direction and another thread turning in a second, generally opposite direction. In fact, no component of the syringe depicted in Fig. 8 has a thread turning in a first direction and another thread turning in a second, generally opposite direction. *See* Novacek, col. 14, ll. 46 – col. 15, l. 46.

Similarly, the cap depicted in Fig. 5 of Novacek has no thread and fits over the hub (6) as shown in the figure. The hub (6) in Fig. 5 does not have a thread turning in a first direction and another thread turning in a second generally opposite direction. Instead, the hub (6) in Fig. 5 has a male thread that "screws into female thread" (88) of the engagement mechanism (80). *See* Novacek, col. 14, ll. 20-31.

Novacek fails to disclose or suggest a protective cap having a cannula support having a thread turning in a first direction and another thread turning in a second direction and, further, a protective cap having a thread engageable with the thread turning in the second direction. Thus,

claim 4 is not anticipated by Novacek. Reconsideration and withdrawal of the rejection are requested.

Claims Depending From Claim 4 Are Patentable

Because claims 2 and 5-8 depend directly or indirectly from claim 4 and incorporate all the limitations of claim 4, they are also not anticipated by Novacek. Reconsideration and withdrawal of these rejections are requested.

Claim 9 Is Not Anticipated By Novacek

Claim 9 is directed to a cannula support comprising a protective cap, wherein at least one latching element is provided on said cannula support and at least one corresponding latching element is provided on said protective cap, the latching elements cooperating to create a latching connection between the cannula support and the protective cap.

Novacek, in contrast, discloses a syringe having a needle that can be retracted into the barrel of the syringe. It is asserted in the Office Action that Fig. 4 of Novacek depicts a cannula support comprising a protective cap, wherein at least one latching element is provided on said cannula support and at least one corresponding latching element is provided on said protective cap. However, there is no cap depicted in Fig. 4. Instead, Fig. 4 depicts a syringe having a hub (6) through which the needle (2) is disposed and through which the needle (2) can be pulled into the interior of the barrel (8). *See* Novacek, Fig. 4. Thus, Fig. 4 does not disclose or suggest the invention of claim 9.

None of the rest of the figures in Novacek disclose or teach the invention of claim 9. For example, neither the cap (32) depicted in Figs. 8, 16, 17, 19, 21, and 32, nor the needle guard (151) depicted in Fig. 34 include a latching element. Instead, cap (32) simply “fits over” the hub (6) as discussed above. *See* Novacek, col. 14, ll. 66-67. Further, cap (151) has threads instead of a latching element. *See* Novacek, Figs. 33 and 34.

Novacek fails to disclose or suggest a latching element provided on a cannula support and a corresponding latching element provided on a protective cap as set forth in claim 9. Reconsideration and withdrawal of the rejection are requested.

Claim 18 Is Not Anticipated By Novacek

Claim 18 is directed to a method for covering a cannula carried by a cannula support using a cannula protecting cap, wherein the cannula support comprises a latching element. Further, the cannula is temporarily covered when the protecting cap is coupled to the cannula support but not to the latching element and permanently covered when the protecting cap is coupled to the latching element.

It is asserted in the Office Action that claims 12 and 15 of Novacek are directed to the invention of claim 18 of the present invention. However, claims 12 and 15 of Novacek are not directed to a cannula support comprising a latching element, because, as discussed above, no latching element is disclosed in Novacek. Further, claims 12 and 15 of Novacek do not disclose or suggest a cannula that is temporarily covered when the protecting cap is coupled to the cannula support but not to the latching element and permanently covered when the protecting cap is coupled to the latching element. That is, the device in claim 12 of Novacek is directed to a syringe having an adapter that is “detachably connected to the distal end of the barrel by a threaded connection.” It is not directed to, nor does it disclose or suggest, a protecting cap. Further, the device in claim 15 of Novacek is directed in part to “a needle guard releasably and sealingly connected adjacent the distal end of the barrel whereby the seal provided by the needle guard and seal structure . . . is sufficient to maintain sterile conditions within the syringe.” The needle guard is either sealingly connected to the end of the barrel or it is not connected. Claim 15 is not directed to, nor does it disclose or suggest, a cannula that is temporarily covered when the protecting cap is coupled to the cannula support but not to the latching element and permanently covered when the protecting cap is coupled to the latching element.

Thus, Novacek fails to disclose or suggest the invention of claim 18. Reconsideration and withdrawal of the rejection are requested.

Claim 19 Is Not Anticipated By Novacek

Claim 19 is directed to a needle cover comprising, in part, an inner protective cap and an outer protective cap.

It is asserted in the Office Action that Fig. 4 of Novacek depicts a needle cover comprising, in part, an inner protective cap and an outer protective cap. However, as discussed above, there is no cap depicted in Fig. 4. That is, while claim 19 of the present application is directed to both an inner protective cap and an outer protective cap, Fig. 4 does not depict even

one cap. Instead, Fig. 4 depicts a syringe having a hub (6) through which the needle (2) is disposed and through which the needle (2) can be pulled into the interior of the barrel (8). *See* Novacek, Fig. 4. Thus, Fig. 4 does not disclose or suggest the invention of claim 19. Further, no figures or discussion in Novacek discloses or suggests an inner protective cap and an outer protective cap as claimed in claim 19. Thus, Novacek fails to disclose or suggest the invention of claim 19, and reconsideration and withdrawal of the rejection are requested.

§ 102(b) Rejection of Claims 9-14

Claims 9-14 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,379,337 ("Mohammad").

Claim 9 Is Not Anticipated By Mohammad

Claim 9 is directed to a cannula support comprising a protective cap, wherein at least one latching element is provided on said cannula support and at least one corresponding latching element is provided on said protective cap, the latching elements cooperating to create a latching connection between the cannula support and the protective cap.

Mohammad, in contrast, fails to disclose or suggest a protective cap. Rather, Mohammad discloses a retractable safety needle that can be moveably positioned in a sheath. *See* Mohammad, Abstract and Fig. 9. It is asserted in the Office Action that Figures 4 and 5a of Mohammad depict a cannula support comprising a protective cap, wherein at least one latching element is provided on said cannula support and at least one corresponding latching element is provided on said protective cap. However, there is no cap depicted in Figure 4 or 5a. Instead, those figures depict a hub (2) that can be connected to the needle (1) such that a user can utilize the thumbrest (8) to move the needle (1) within the sleeve 15, as best depicted in Figure 9. *See* Mohammad, col. 5, l. 58 – col. 6, l. 10 and col. 7, l. 27 – col. 8, l. 14. The needle (1) "extends from one end of [the] hub (2), and penetrates the second end of the hub." *Id.* at col. 5, ll. 22-23. That is, the hub (2) is not a protective cap, but rather a component for use in moving the needle. Thus, Mohammad fails to disclose or suggest a protective cap as claimed in claim 9, and reconsideration and withdrawal of the rejection are requested.

Claims Depending From Claim 9 Are Patentable

Because claims 10-17 depend directly or indirectly from claim 9 and incorporate all the limitations of claim 9, the above remarks about Mohammad apply to these claims as well. Reconsideration and withdrawal of the rejections are requested.

New Claims 20-26 Are Patentable

New independent claim 20 is directed to a cannula system comprising a cannula support, an inner protective cap, and an outer protective cap.

New claim 20 is patentable over Novacek and Mohammad because neither discloses or suggests an inner protective cap and an outer protective cap.

Because claims 21-26 depend directly or indirectly from claim 20 and incorporate all the limitations of claim 20, they are allowable for the same reasons, further in view of their additional recitations.

Conclusion

The submission of this paper generates new claim fees in the amount of \$200.00. Applicant submits a check to cover the necessary fees. Applicant also submits herewith a Petition for Extension of time along with a check in the amount of \$120.00 to cover the necessary fees. The Commissioner is authorized to charge any deficiencies and/or credit any overpayment to Deposit Account No. 04-1420.

The application is now in condition for allowance, and reconsideration and a Notice of Allowance are requested.

Respectfully submitted,

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